Investigator's Responsibilities to Combined Monitoring Board

Monitoring multi-site intervention studies (clinical trials) is an important function of the HSR&D Combined Monitoring Board (CoMB), composed of HSR&D researchers, epidemiologists, biostatisticians, and health economists. The CoMB provides a continuing critical and unbiased evaluation of the study's progress, with particular attention to human subjects and data analysis. This Board will perform many of the functions of a Data and Safety Monitoring Board. The Board's major responsibilities are to:

- Review the data analysis plan
- Review the patient accrual and patient follow-up record
- Assess performance of each participating site
- Review Serious Adverse Events (SAEs)

A data analysis plan is requested from the Principal Investigators (due within 30 days of funding) of all newly-funded multi-site, intervention trials that are under the jurisdiction of more than one IRB, include human subjects in the study, and involve randomization**.** The description of the data analysis plan should summarize all of the statistical analyses for the primary, and important secondary, hypotheses or research questions specified in the original proposal. It should include a discussion of each of the following points applicable to the study:

- The rationale for the study sample size
- The method of randomization (describing any stratification and blocking techniques)
- Plans for and specification of the purpose of any interim looks at the data (with regards to stopping rules for superiority, futility, or sample size re-estimation)
- Methods for handling missing data points and subject dropouts
- Definitions of covariates to be included in adjustment models
- Methods for dealing with data transformations
- Definitions of the analytical sets (i.e. intent-to-treat, per-protocol, and any other analytical subsets)

As the principal investigator of a multi-site intervention study, you also will be asked to prepare and submit a report about 3 weeks prior to the CoMB annual meeting and to present your study for review by the CoMB at their annual meeting. The Palo Alto Cooperative Studies Program Coordinating Center (CSPCC) is responsible for coordination of the CoMB meetings, which have been held in San Francisco, CA; they will be in contact with information about this review.

The Combined Monitoring Board Guidelines are posted at this Website. If you have questions about the requirements of the CoMB, please contact Martha Bryan, EdD in HSR&D at 202-254-0251 or martha.bryan@va.gov.